

INSURANCE DIVISION[191]

Adopted and Filed

Rule making related to pharmacy benefits managers

The Insurance Division hereby amends Chapter 59, “Pharmacy Benefits Managers,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code chapters 510, 510B and 510C and 2022 Iowa Acts, House File 2384, section 22.

State or Federal Law Implemented

This rule making implements, in whole or in part, 2022 Iowa Acts, House File 2384.

Purpose and Summary

These amendments update Chapter 59 to implement changes made in 2022 Iowa Acts, House File 2384, regarding pharmacy benefits managers. This rule making adds new definitions for “dosage unit,” “ingredient costs,” “prescription drug cost reimbursement fee,” and “wholesale acquisition cost.” This rule making also adds provisions regarding penalties and the pharmacy benefits manager annual report.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on January 11, 2023, as **ARC 6825C**. A public hearing was held on February 2, 2023, at 1 p.m. at 1963 Bell Avenue, Suite 100, Des Moines, Iowa.

The Division received oral and written comments from the Iowa Pharmacy Association (IPA) and the Pharmaceutical Care Management Association (PCMA). The Division also received combined written comments from the National Association of Chain Drug Stores (NACDS) and the National Association of Specialty Pharmacy (NASP).

Concerns were expressed regarding the inclusion of certain definitions, the manner in which certain terms were defined and the content of the annual report.

Definitions for “brand-name drug,” “generic drug” and “specialty drug” were not adopted and a new definition for “dosage unit” was adopted based on comments received by the Division. Time frames were adjusted for consistency with other Division rules regarding submission of the quarterly complaint summary. The Division also made changes to the content of the annual report required for submission by pharmacy benefits managers to ensure that the information requested is in accordance with statutorily defined terminology and eliminated references to reporting information based on the national business of a pharmacy benefits manager.

Adoption of Rule Making

This rule making was adopted by Douglas Ommen, Iowa Insurance Commissioner, on May 24, 2023.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Division for a waiver of the discretionary provisions, if any, pursuant to 191—Chapter 4.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its [regular monthly meeting](#) or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on July 19, 2023.

The following rule-making action is adopted:

ITEM 1. Adopt the following **new** definitions of “Dosage unit,” “Ingredient costs,” “Prescription drug cost reimbursement fee” and “Wholesale acquisition cost” in rule **191—59.2(510B)**:

“*Dosage unit*” means the same as defined in 45 CFR Section 149.710.

“*Ingredient costs*” means the costs of the component of the prescription drug for prescriptions dispensed. Ingredient costs do not include dispensing fees, copayments received by the pharmacy, service fees or any other type of reimbursement paid to the pharmacy by a pharmacy benefits manager.

“*Prescription drug cost reimbursement fee*” means the dollar amount reimbursed by a third-party payor to the pharmacy benefits manager for the ingredient costs of a prescription drug. The prescription drug cost reimbursement fee may be a type of third-party payor administrative service fee.

“*Wholesale acquisition cost*” means the same as defined in 42 U.S.C. Section 1395w-3a(c)(6)(B).

ITEM 2. Adopt the following **new** subrule 59.8(5):

59.8(5) Penalties. A pharmacy benefits manager that fails to timely submit to the commissioner a complete quarterly complaint summary shall pay a late fee of \$100. If a pharmacy benefits manager fails to submit a complete quarterly complaint summary within 30 days after the calendar quarter has ended, the pharmacy benefits manager may be subject to penalties as set forth in rule 191—59.12(505,507,507B,510,510B,510C,514L).

ITEM 3. Renumber subrules **59.11(4)** to **59.11(6)** as **59.11(5)** to **59.11(7)**.

ITEM 4. Adopt the following **new** subrule 59.11(4):

59.11(4) Report content.

a. Reporting requirement elements.

(1) A pharmacy benefits manager shall provide information about all rebates, as defined in Iowa Code section 510C.1, which shall include but not be limited to any consideration, incentive, disbursement, discount, payment and any other pecuniary transaction that is provided directly or indirectly to the pharmacy benefits manager from a pharmaceutical manufacturer that adjusts the price of the wholesale acquisition cost of a prescription drug.

(2) An administrative fee, as defined in Iowa Code section 510C.1, shall include but not be limited to any consideration, incentive, disbursement, payment and any other pecuniary transaction, other than a rebate, that is provided directly or indirectly to the pharmacy benefits manager from a pharmaceutical manufacturer.

(3) The aggregate dollar amount of a rebate shall be reported as the wholesale acquisition cost of a prescription drug minus the price negotiated by the pharmacy benefits manager for the same prescription drug.

(4) Aggregate dollar amounts reported shall be reported as gross aggregate dollar amounts using generally accepted accounting principles (GAAP).

(5) Information requested about pharmacies shall include any pharmacy services administrative organizations that may represent pharmacies.

(6) A third-party payor administrative service fee, as defined in Iowa Code section 510C.1, shall include but not be limited to any consideration, incentive, disbursement, payment and any other pecuniary transaction that is provided directly or indirectly to the pharmacy benefits manager from a third-party payor.

(7) A third-party payor administrative service fee, as defined in Iowa Code section 510C.1, shall not be reported as a benefit or incurred claim provided under a health benefit plan.

b. Information required under Iowa Code section 510C.2(1) "a" shall include:

(1) The aggregate dollar amount of all rebates received by the pharmacy benefits manager, either directly or indirectly through a proxy, contractor, subsidiary or parent company, for its business in Iowa.

(2) The rebate amounts received, based on the information reported in subparagraph 59.11(4) "b"(1), for each of the top prescription drugs for which the pharmacy benefits manager received the highest dollar amount of rebates from the pharmaceutical manufacturer.

1. Report the aggregate dollar amount of the rebate for each of the top prescription drugs reported pursuant to subparagraph 59.11(4) "b"(2).

2. Report the aggregate dollar amount of the rebate that was:

- Passed through to a third-party payor;
- Passed through to enrollees at the point of sale of a prescription drug; and
- Retained by the pharmacy benefits manager.

(3) The rebate amounts received, based on the information reported in subparagraph 59.11(4) "b"(1), for each of the top prescription drugs dispensed based on volume of dosage units for which the pharmacy benefits manager reimbursed pharmacies.

1. Report the aggregate dollar amount of the rebate for each of the top prescription drugs reported pursuant to subparagraph 59.11(4) "b"(3).

2. Report the aggregate dollar amount of the rebate that was:

- Passed through to a third-party payor;
- Passed through to enrollees at the point of sale of a prescription drug; and
- Retained by the pharmacy benefits manager.

c. Information required under Iowa Code section 510C.2(1) "b" shall include the aggregate dollar amount of all administrative fees received by the pharmacy benefits manager, either directly or indirectly through a proxy, contractor, subsidiary or parent company, for its business in Iowa.

d. Information required under Iowa Code section 510C.2(1) "c" shall include:

(1) The aggregate dollar amount of all third-party payor administrative service fees received by the pharmacy benefits manager, either directly or indirectly through a proxy, contractor, subsidiary or parent company, for its business in Iowa.

(2) The aggregate dollar amount of all prescription drug cost reimbursement fees received by the pharmacy benefits manager, either directly or indirectly through a proxy, contractor, subsidiary or parent company, for its business in Iowa.

(3) The aggregate prescription drug cost reimbursement fee, based on the top prescription drugs reported in subparagraph 59.11(4) "b"(2), received for each drug that was:

1. Paid to the pharmacies as reimbursement from the pharmacy benefits manager for the ingredient costs of prescriptions dispensed by the pharmacies.

2. Retained by the pharmacy benefits manager.

e. Information required under Iowa Code section 510C.2(1) "d" shall include the aggregate dollar amount of all rebates received by the pharmacy benefits manager that the pharmacy benefits manager did not pass through to the third-party payor through its business in Iowa that is conducted either directly or indirectly through a proxy, contractor, subsidiary or parent company.

f. Information required under Iowa Code section 510C.2(1) "e" shall include the aggregate dollar amount of all administrative fees received by the pharmacy benefits manager that the pharmacy benefits

manager did not pass through to the third-party payor through its business in Iowa that is conducted either directly or indirectly through a proxy, contractor, subsidiary or parent company.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/14/23.